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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,638	01/22/2002	Robert P. Ryall	01-059-A	9398

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EXAMINER	
DEVI, SARVAMANGALA J N	
ART UNIT	**PAPER NUMBER**
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/054,638	RYALL, ROBERT P.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-36,46,48-51,56 and 57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-36,46,48-51,56 and 57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Request for Continued Examination

1) A request for continued examination under 37 C.F.R 1.114, including the fee set forth in 37 C.F.R 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R 1.114, and the fee set forth in 37 C.F.R 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R 1.114. Applicant's submission filed on 09/20/07 has been entered.

Applicant's Amendment

2) Acknowledgment is made of Applicant's amendment filed 09/20/07 in response to the final Office Action mailed 03/20/07.

Status of Claims

3) Claims 18, 19, 22, 29 and 35 have been amended via the amendment filed 09/20/07.

Claims 18-36, 46, 48-51, 56 and 57 are pending and are under examination.

Prior Citation of Title 35 Sections

4) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

5) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Maintained

6) The objection to the specification made in paragraph 5 Office Action mailed 10/03/05 and maintained in paragraph 5 of the Office Action mailed 03/20/07 under 35 U.S.C. § 132 as introducing new matter, is maintained for reasons set forth therein.

Applicant alleges that the Office refused to enter the proposed amendment to the specification. Applicant further states that he 'withdraws' the proposed amendment without prejudice and concludes that the objection to the specification is therefore moot.

First, the Office did not refuse to enter the amendment to the specification filed 06/07/05. Instead, said amendment to the specification was objected to under 35 U.S.C. § 132 as introducing new matter. It is noted that Applicant has *not* removed the identified new matter from paragraph

[0033] of the specification as amended via the amendment filed 06/07/05 via submission of a new amendment to paragraph [0033] along with the instant RCE request. The objection stands.

Rejection(s) Withdrawn

7) The rejection of claim 19 made in paragraph 20(b) of the Office Action mailed 12/07/04 and maintained in paragraph 44 of the Office Action mailed 10/03/05 and paragraph 25 of the Office Action mailed 03/20/07 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claim.

8) The rejection of claim 22 made in paragraphs 32(a) and 32(b) of the Office Action mailed 03/20/07 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claim.

9) The rejection of claims 23-25 made in paragraph 32(c) of the Office Action mailed 03/20/07 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the base claim.

10) The rejection of claim 29 made in paragraph 53(i) of the Office Action mailed 10/03/05 and maintained in paragraph 29 of the Office Action mailed 03/20/07 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claim.

11) The rejection of claims 30-32 and 36 made in paragraph 53(q) of the Office Action mailed 10/03/05 and maintained in paragraph 30 of the Office Action mailed 03/20/07 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn.

12) The rejection of claim 35 made in paragraph 53(m) of the Office Action mailed 10/03/05 and maintained in paragraph 31 of the Office Action mailed 03/20/07under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claim.

Rejection(s) Maintained

13) The rejection of claims 18-33 and 51 made in paragraph 22 of the Office Action mailed 12/07/04 and maintained in paragraph 47 of the Office Action mailed 10/03/05 and paragraph 26 of the Office Action mailed 03/20/07 under 35 U.S.C. § 103(a) as being unpatentable over McMaster (US 6,146,902 – Applicants' IDS submitted 07/07/04) in view of Andre *et al.* (*In*: *Modern Vaccinology*. (Ed) Kurstak *et al.* Plenum Medical Book Company, New York, pp. 41-54, 1994, already of record), Levine *et al.* (*In*: *Abstracts of the Tenth International Pathogenic Neisseria*

Conference, (Ed) Zollinger *et al.* Baltimore, USA, pages 228-230, November, 1997, already of record) and Lindberg AA (*Vaccine* 17: S28-S36, 1999 – Applicants' IDS), is withdrawn in light of Applicant's amendment to the base claim. A new rejection is set forth below to address the claims as amended. Applicant's arguments with regard to this art rejection have been considered but are moot in view of Applicant's amendment to the base claim and the resultant new ground(s) of rejection set forth below. Applicant is hereby advised that if the claim(s) is amended to delete the above-identified new matter with no further amendments to the claim, the instant art rejection would be reinstated.

14) The rejection of claims 18-36, 46, 48-51, 56 and 57 made in paragraph 23 of the Office Action mailed 12/07/04 and maintained in paragraph 48 of the Office Action mailed 10/03/05 and paragraph 27 of the Office Action mailed 03/20/07 under 35 U.S.C § 103(a) as being unpatentable over Costantino *et al.* (*Vaccine* 10: 691-698, 1992, already of record) and McMaster (US 6,146,902 – Applicants' IDS submitted 07/07/04) in view of Andre *et al.* (*In*: *Modern Vaccinology*. (Ed) Kurstak *et al.* Plenum Medical Book Company, New York, pp. 41-54, 1994, already of record); Levine *et al.* (*In*: *Abstracts of the Tenth International Pathogenic Neisseria Conference*, (Ed) Zollinger *et al.* Baltimore, USA, pages 228-230, November, 1997, already of record) and Lindberg AA (*Vaccine* 17: S28-S36, 1999 – Applicants' IDS), is withdrawn in light of Applicant's amendment to the base claim. A new rejection is set forth below to address the claims as amended. Applicant's arguments with regard to this art rejection have been considered but are moot in view of Applicant's amendment to the base claim and the resultant new ground(s) of rejection set forth below. Applicant is hereby advised that if the claim(s) is amended to delete the above-identified new matter with no further amendments with no further amendments to the claim, the instant art rejections would be reinstated.

Rejection(s) under 35 U.S.C. § 112, First Paragraph (New Matter)

15) Claim 18 and the dependent claims 19-36, 46, 48-51, 56 and 57 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970) and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 C.F.R 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R 3.73(b).

15) Claims 18-33 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claim 56 of the co-pending application 11232160. Although the conflicting claims are not identical, they are not patentably distinct from each other because the product of claim 56 of the co-pending application, being drawn to a polysaccharide-protein conjugate composition comprising two or more capsular polysaccharides of *N. meningitidis* serogroups A and W-135; Y and W-135; Y, C and W-135; A and C; Y, A, C and W-135; A, Y and W-135; or A, C, Y and W-135, conjugated to one or more carrier proteins, falls within the scope of the instant claims.

This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Rejection(s) under 35 U.S.C. § 112, First Paragraph (New Matter)

16) Claim 18 and the dependent claims 19-36, 46, 48-51, 56 and 57 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 18, as amended, includes the new generic limitation: 'mammal'. Claim 18, as amended, includes the new limitation: 'said immunogenic composition is capable of eliciting an immune response in a mammal to *one or* more of said polysaccharides' [Emphasis added]. Applicant does not point to specific parts of the specification that provide support for the new limitation. The new generic limitation 'mammal' in the base claim 18 is not limited to a human, mouse, rat, or rabbit species, but encompasses a number of other mammalian species including monkeys, chimpanzees, horses, dogs, cats, guinea pigs, deer, cattle, sheep, goats, pigs etc. The

instant specification does not provide support for such a genus. The specific mammalian species recited in the specification do not provide adequate descriptive support for the above-identified broad genus. Furthermore, the immunological composition in the amended claim encompasses an immunological composition that is required to comprise a combination of 2, 3, or 4 separately made protein-capsular polysaccharide conjugates from serogroup A, C, W-135 and Y wherein at least one serogroup is required to be W-135 or Y, and having the capacity to elicit an immune response in a mammal selectively to only one, only two, or only three of said capsular polysaccharides. However, such a bivalent, trivalent or tetravalent conjugate having the unique capacity to elicit an immune response selectively to only one of the two, three or four recited serogroup capsular polysaccharides, only two of the three or four recited serogroup capsular polysaccharides, or only three of the four recited serogroup capsular polysaccharides, but not to the rest of the recited serogroup capsular polysaccharides, lacks descriptive support in the specification, as originally filed. Therefore, the above-identified new limitations in the instant claims are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P. 608.04 to 608.04(c).

Applicant is invited to point to specific line and page numbers of the specification, as originally filed, that provide descriptive support for the limitations identified above, or alternatively to remove the new matter from the claim(s). Applicant should specifically point out the support for any amendments made to the disclosure. See MPEP 714.02 and 2163.06.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

17) Claims 22-25, 35, 36 and 38-50 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite, for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

(a) Claim 22 lacks proper antecedent basis and is inconsistent with claims 26, 29 and 33 in the limitation: 'combination of two distinct separately made protein-capsular polysaccharide conjugates' (see line 2). For consistency and proper antecedent basis, it is suggested that Applicant replace the above-identified limitation with the limitation --combination of said two distinct separately made protein-capsular polysaccharide conjugates--.

(b) Claim 35 is vague and indefinite in the limitation: 'said adjuvant comprises an

aluminum adjuvant', because it is unclear how aluminum adjuvant can be 'comprised' within another generic adjuvant. For the purpose of distinctly claiming the subject matter, it is suggested that Applicant replace the above-identified limitation with the limitation --said adjuvant is an aluminum adjuvant--.

(c) Analogous rejection and criticism apply to claim 48 with regard to the limitation: 'said single carrier protein species comprises an inactivated bacterial toxin' as opposed to the limitation --said single carrier protein species is an inactivated bacterial toxin--.

(d) Claim 48 is vague and indefinite in the use of the abbreviated limitations: 'LT' and 'ST' in the claim language. It is suggested that each abbreviation be recited as a full terminology while retaining the abbreviation within parentheses.

(e) Claims 23-25, which depend from claim 22, claim 36 which depends from claim 35, and claims 49 and 50 which depend from claim 48, are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

Rejection(s) under 35 U.S.C. § 103

18) Claims 18-36, 46 and 48-51 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Costantino *et al.* (*Vaccine* 10: 691-698, 1992, already of record) in view of McMaster (US 6,146,902, already of record), Chong *et al.* (WO 99/42130, already of record), Lingappa *et al.* (*Vaccine* 19: 4566-4575, August 2001), Perkins BA (*JAMA* 283: 2842-2843, 07 June 2000), Morley *et al.* (*Vaccine* 20: 666-687, 12 December 2001).

Instant claims are granted the effective filing date of the instant application due to the new matter identified above.

The transitional term 'comprising', which is synonymous with 'including', 'containing', or 'characterized by', is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. *Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986)*; *In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981)*; and *Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948)* ('comprising' leaves 'the claim open for the inclusion of unspecified ingredients even in major amounts').

Costantino *et al.* taught a vaccine composition comprising two distinct protein-polysaccharide conjugates, wherein the first conjugate comprises a purified meningococcal serogroup A capsular polysaccharide conjugated to CRM 197 and a second conjugate comprises a

purified meningococcal serogroup C capsular polysaccharide conjugated to CRM 197. The conjugate comprises an aluminum hydroxide adjuvant. The conjugate vaccine in phosphate buffer (i.e., liquid) is sterile-filtered. The vaccine composition induced a significant increase in antibodies to group A and C meningococcal capsular polysaccharides. Costantino *et al.* first produced the individual serogroup A polysaccharide-CRM 197 and serogroup A polysaccharide-CRM 197 conjugates, and then produced the combined conjugate vaccine. See abstract; Materials and Methods; Results; Figures 5 and 6; and Table 2.

The conjugate vaccine of Costantino *et al.* differs from the instant invention in not containing meningococcal W-135 and/or Y capsular polysaccharide conjugate(s) therein.

However, individually produced meningococcal serogroup W135 or Y capsular polysaccharide-protein conjugate vaccine was already known in the art at the time of the instant invention. For example, McMaster disclosed individually made purified meningococcal W-135 and Y capsular polysaccharide-protein carrier conjugate vaccines and provided detailed teachings as to how to successfully make the individual purified meningococcal W-135 and Y capsular polysaccharide-protein carrier conjugates in addition to making purified meningococcal A and C capsular polysaccharide-protein carrier conjugates. McMaster disclosed a vaccine or immunological composition comprising a sterile liquid solution of individual capsular polysaccharide-protein conjugates comprising purified capsular polysaccharides of *Neisseria meningitidis* belonging to the serogroup A, C, W-135 and Y conjugated to diphtheria toxoid protein for human or animal use. Column 7; Table 3; lines 59-64 of column 3; paragraph bridging columns 3 and 4; and lines 3-6 in column 4. The serogroup A, C, W-135 and Y meningococcal capsular polysaccharide conjugates are identified by their lot numbers as D01886, D01887, D01889 and D01880 respectively. See Table 3. The production of meningococcal serogroup A, C, Y and W-135 conjugates are described in columns 6 and 7; and Example 1.

Furthermore, the concept of including, in a multivalent immunogenic conjugate vaccine formulation, the meningococcal serogroup W-135 or Y capsular polysaccharide along with meningococcal serogroup A and C capsular polysaccharides in conjugate form, was already known in the art at the time of the invention. For example, Chong *et al.* had already established reasonable expectation of success with a multivalent immunogenic molecule comprising multiple purified capsular polysaccharides or oligosaccharides of *Neisseria meningitidis* derived from serogroup A, C, W-135 and Y, each conjugated to a carrier protein for use as a medicament against meningitis. See

claims 1, 6-8, 39 and 40; paragraph bridging pages 9 and 10; pages 10 and 12; and Examples 1, 2 and 4 of Chong *et al.*

Lingappa *et al.* expressly taught that the proportion of meningococcal disease caused by serogroup Y has risen dramatically in the US over the past decade. Lingappa *et al.* determined that addition of a serogroup Y conjugate to a serogroup C conjugate vaccine used with an infant strategy could result in 48% greater reduction in meningococcal disease. Similarly, Lingappa *et al.* predicted the serogroup W135 to rise to greater prominence in US and world-wide. Lingappa *et al.* further expressly taught that uncertainties in the future importance of serogroups A/C/Y/W-135 conjugate vaccine formulation make the broader A/C/Y/W-135 conjugate vaccine formulation *appealing for the greater flexibility* it would provide in the face of future changes in US serogroup distribution. Lingappa *et al.* explicitly taught that such a vaccine could also be used internationally despite variations in the global distribution of meningococcal serogroups. See paragraph bridging the two columns on page 4572.

Likewise, Perkins expressly included meningococcal serogroups A, C, Y and W-135 in the list of globally most important causes of meningococcal disease. See third full paragraph on page 2842. Perkins taught that because of the variation in serogroup distribution by region and age and potential for capsular switching, there is an identified need for development and availability of *multivalent* meningococcal conjugates, with some or all of meningococcal serogroups A, C, Y and W-135, as stand-alone vaccines and in combination with other vaccines. Perkins expressly suggested the inclusion of A, C, Y and W-135 serogroups in conjugate meningococcal vaccines as the broadest approach based on the current understanding of *N. meningitidis*. See last two full paragraphs on page 2843.

Morley *et al.* provided the following express teaching (see lines 11-14 of second full paragraph in column 2 of page 670):

> There is every reason to expect that A, C, Y and W135 meningococcal conjugate vaccines will be as successful as the *H. influenzae* glycoconjugates in preventing disease caused by the serogroups from which they are derived.

Morley *et al.* further taught that the likelihood of occurrence of capsular switching would be minimized by vaccination against multiple serogroups by development of *combination* A, C, Y and W135 conjugates. See last full paragraph on page 670.

With the concept of providing meningococcal serogroups A, C Y and W-135 capsular polysaccharide-protein conjugates in a multivalent immunogenic formulation already known in the

art as taught by Chong *et al.* and given that individually produced purified meningococcal serogroup Y and W-135 capsular polysaccharide-protein conjugates were already known in the art as taught by McMaster, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine McMaster's individually produced purified meningococcal serogroup Y and/or W-135 capsular polysaccharide-protein conjugates with Costantino's meningococcal combination conjugate vaccine comprising meningococcal serogroup A + C capsular polysaccharide-protein conjugates to produce the instant invention. With the identified need in the art for development and availability of *multivalent* meningococcal conjugates, with some or all of meningococcal serogroups A, C, Y and W-135, as stand-alone vaccines and in combination with other available vaccines as expressly taught by Perkins, and with the reasonable expectation of success already expected in the art with A, C, Y and W135 meningococcal conjugate vaccines as taught by Morley *et al.*, one of ordinary skill in the art would have been motivated to produce the instant invention for the expected benefit of providing a multivalent combination meningococcal capsular polysaccharide conjugates of serogroups A, C, Y and W-135, wherein at least one of the serogroup is W-135 or Y in order to minimize the likelihood of occurrence of capsular switching as taught by Morley *et al.* and to provide an appealing, greatly flexible, broader A/C/Y/W-135 conjugate vaccine formulation as taught by Lingappa *et al.*

Claims 18-36, 46 and 48-51 are *prima facie* obvious over the prior art of record.

19) Claims 56 and 57 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Costantino *et al.* (*Vaccine* 10: 691-698, 1992, already of record) as modified by McMaster (US 6,146,902, already of record), Chong *et al.* (WO 99/42130), Lingappa *et al.* (*Vaccine* 19: 4566-4575, August 2001), Perkins BA (*JAMA* 283: 2842-2843, 07 June 2000), Morley *et al.* (*Vaccine* 20: 666-687, 12 December 2001) as applied to claims 33 and 18 above, and further in view of Schneerson *et al.* (US 6,632,437, already of record).

The reference of Schneerson *et al.* is applied in this rejection because it qualifies as prior art under subsection (e) of 35 U.S.C § 102 and accordingly is not disqualified under U.S.C 103(a).

The teachings of Costantino *et al.* as modified by McMaster, Chong *et al.*, Lingappa *et al.*, Perkins, and Morley *et al.* are explained above which do not expressly teach the presence of thimerosal preservative in their multivalent immunogenic conjugate vaccine.

However, it was very routine and conventional in the art at the time the invention was made to add an art-known pharmaceutically acceptable preservative such as thimerosal to a conjugate

vaccine. For instance, Schneerson *et al.* taught the addition of 0.01% thimerosal preservative to a capsular polysaccharide conjugate vaccine for safe storage. See the paragraph above Example 1.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to add Schneerson's thimerosal preservative to Costantino's multivalent immunogenic conjugate vaccine as modified by McMaster, Chong *et al.*, Lingappa *et al.*, Perkins, and Morley *et al.* to produce the instant invention with a reasonable expectation of success. One of ordinary skill in the art would have been motivated to produce the instant invention for the expected benefit of proper storage of the vaccine as taught by Schneerson *et al.*

Claims 56 and 57 are *prima facie* obvious over the prior art of record.

Relevant Prior Art

20 The prior art made of record and not relied upon in any of the rejections is considered pertinent to Applicant's disclosure:

- Tai *et al.* (*Abstracts of the Tenth International Pathogenic Neisseria Conference*, (Ed) Zollinger *et al.* September 8-13, Baltimore, USA, pages 214-215, 1996) taught a trivalent combination vaccine comprising individual meningococcal serogroup A, B and C conjugates and its preclinical evaluation in monkeys. The combination conjugate vaccine elicited bactericidal antibodies to capsular polysaccharides of all the three meningococcal serogroups after only one injection of the trivalent formulation. Thus, the concept of combining two or more individually produced meningococcal capsular polysaccharide-protein conjugates in a multivalent conjugate formulation which elicited bactericidal antibodies to each of the serogroup capsular polysaccharides including the serogroup B capsular polysaccharide in immunized monkeys. Tai *et al.* already established reasonable expectation of success of combining three different meningococcal serogroup capsular polysaccharide-protein conjugates including the serogroup B capsular polysaccharide to produce an immunogenic combination conjugate vaccine and reported no unpredictability and no indication of carrier-induced epitopic suppression associated with such a combination vaccine. See pages 214 and 215.

Remarks

21) Claims 18-36, 46, 48-51, 56 and 57 stand rejected.

22) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile

transmission. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

23) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

24) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Shanon Foley, can be reached on (571) 272-0898.

December, 2007

S. DEVI, PH.D.
PRIMARY EXAMINER